CLAIMS

1. A method for determining the biological effect and/or activity of at least one drug, chemical substance and/or pharmaceutical composition, comprising the steps of:
(a) obtaining a biological sample A containing DNA from at least one individual, tissue, cell or other biological material containing DNA, which was exposed to said at least one drug, chemical substance and/or pharmaceutical composition;
(b) obtaining a biological sample B containing DNA from at least one individual, tissue, cell or other biological material containing DNA, which was not exposed to said at least one drug, chemical substance or pharmaceutical composition;
(c) analysing the level of cytosine methylation at chosen sites of the DNA contained in the samples A and B;
(d) selecting the sites which are differentially methylated between the DNA in samples A and B,
whereby a knowledge base is generated; and
(e) concluding from the said knowledge base on the biological effect and/or activity of said at least one drug, chemical substance or pharmaceutical composition.

2. Method according to claim 1, comprising that the biological sample is obtained by means of a biopsy, by means of an operation on an individual, by means of a dissection, derived from a preserved biological sample, collected from body fluid(s) and/or collected directly from the environment.

3. Method according to claim 1 or 2, characterised in that the biological sample comprises a eucaryotic and/or procaryotic cell line, a biopsy sample, blood, sputum, faeces, urine, cerebral liquid, tissue embedded in paraffin, tissue derived from eyes, intestine, brain, heart, prostata, kidney, lung, breast or liver, histological samples or a combination thereof.

4. Method according to any of claims 1 to 3, characterised in that said biological sample is obtained from biological material of healthy and/or diseased individuals.

5. Method according to any of claims 1 to 4, characterised in that the biological samples A and B are obtained from the identical individual, tissue, cell or other biological material.

6. Method according claim 5, characterised in that the biological samples A and B are taken before, during and/or after onset of a treatment with said drug, chemical substance or pharmaceutical composition.

7. Method according to any of claims 1 to 6, further comprising the step of isolating DNA from the said samples before analysing the level of cytosine methylation at chosen sites in said isolated DNA.

8. Method according to claim 7, characterised in that the isolation of said DNA contained in said biological sample comprises isolating subcellular compartments, organelles, macromolecular structures and multiprotein complexes, partial or complete preparation of the DNA and/or mRNA, reverse transcription or partial digestion of the material with an enzyme selected from proteases, RNAses and/or DNAses or combinations thereof.

9. Method according to any of claims 1 to 8, characterised in that the analysis of the level of cytosine methylation comprises chemical treatment with bisulphite, hydrogen sulphite or disulphite, polymerase chain reaction (PCR), hybridisation analyses, sequencing, mass spectrometry and fluorescent, enzymatic, radioactive, dye and/or antibody labelling.

10. Method according to any of claims 1 to 9, characterised in that all potential methylation sites of the DNA are analysed.

11. Method according to any of claims 1 to 10, characterised in that the level of at least two cytosine methylation sites is analysed in parallel.

12. Method according to claim 11, characterised in that the level of at least 100 cytosine methylation sites is analysed in parallel.

13. Method according to any of claims 1 to 12, characterised in that the methylation sites are located in methylation relevant regions of the DNA comprising complete genes and/or promoters, introns, first exons and/or enhancers.

14. Method according to any of claims 1 to 13, characterised in that the methylation sites are located in methylation relevant regions of genes related with unwanted side effects of medicaments, cancers, dysfunctions, damages or diseases of the central nerval system (CNS), aggressive symptoms or behavioural disorders, clinical, psychological and social consequences of brain injuries, psychotic disorders and disorders of the personality, dementia and/or associates syndromes, cardiovascular diseases, malfunctions or damages, diseases, malfunctions or damages of the gastrointestine, diseases, malfunctions or damages of the respiratory system, injury, inflammation, infection, immunity and/or reconvalescence, diseases, malfunctions or damages as consequences of modifications in the developmental process, diseases, malfunctions or damages of the skin, muscles, connective tissue or bones, endocrine or metabolic diseases, malfunctions or damages, headache, and sexual malfunctions or combinations thereof.

15. Method according to claim 14, characterised in that the

methylation sites are located in methylation relevant regions of genes related with leukemia, head and neck cancer, Hodgkin's disease, gastric cancer, prostate cancer, renal cancer, bladder cancer, breast cancer, Burkitt's lymphoma, Wilms tumor, Prader-Willi/Angelman syndrome, ICF syndrome, dermatofibroma, hypertension, pediatric neurobiological diseases, autism, ulcerative colitis, fragile X syndrome, and Huntington's disease.

16. Method according to any of claims 1 to 15, wherein said analysed methylation sites are disease specific and/or personalised.

17. Method according to any of claims 1 to 16, characterised in that the selection is based on the result of at least two individual rows of analyses.

18. Method according to any of claims 1 to 17, characterised in that the selection is performed in such a way as to give a knowledge base comprising only one set of selected sites.

19. Method according to any of claims 1 to 17, characterised in that the selection is performed in such a way as to give a knowledge base comprising different classes, in particular quality classes of selected sites.

20. Method according to any of claims 1 to 19, characterised in that the selection is at least partially performed automatically by means of a suited automate, such as a computer device.

21. Method according to any of claims 1 to 20, characterised in that at least two sites are selected in parallel.

22. Method according to claim 21, characterised in that at least 100 sites are selected in parallel.

23. Method according to any of claims 1 to 22, characterised in that all or a part of the sites of the knowledge base are used for the conclusion.

24. Method according to any of claims 1 to 23, characterised in that additional information about the biological sample is used for the conclusion.

25. Method according to any of claims 1 to 24, characterised in that the conclusion is based on the result of at least two individual rows of analyses.

26. The method according to any of claims 1 to 25, characterized in that the conclusion is performed by a computer system.

27. Method according to any of claims 1 to 26, characterised in that steps a) to d) are repeated.

28. Method according to any of claims 1 to 27, characterised in that the identical biological sample, different biological samples or a combination thereof is used in steps a) and/or b).

29. Method according to any of claims 1 to 26, characterised in that steps c) to d) are repeated.

30. Method according to any of claims 1 to 29, characterised in that said method is repeated for at least 5 to 50 times.

31. Method according to any of claims 1 to 30, characterised in that said method is at least partially performed by means

of a suited automate, for example a robot and/or a computer system.

32. Use of a method according to any of claims 1 to 31 for determining at least one drug, chemical substance and/or pharmaceutical composition that is biologically effective and/or active.

33. Use according to claim 32, wherein said at least one drug, chemical substance and/or pharmaceutical composition is biologically effective and/or active in the treatment of unwanted side effects of medicaments, cancers, dysfunctions, damages or diseases of the central nerval system (CNS), aggressive symptoms or behavioural disorders, clinical, psychological and social consequences of brain injuries, psychotic disorders and disorders of the personality, dementia and/or associates syndromes, cardiovascular diseases, malfunctions or damages, diseases, malfunctions or damages of the gastrointestine, diseases, malfunctions or damages of the respiratory system, injury, inflammation, infection, immunity and/or reconvalescence, diseases, malfunctions or damages as consequences of modifications in the developmental process, diseases, malfunctions or damages of the skin, muscles, connective tissue or bones, endocrine or metabolic diseases, malfunctions or damages, headache, and sexual malfunctions or combinations thereof.

34. Use according to claim 33, wherein said at least one drug, chemical substance and/or pharmaceutical composition is biologically effective and/or active in the treatment of leukemia, head and neck cancer, Hodgkin's disease, gastric cancer, prostate cancer, renal cancer, bladder cancer, breast cancer, Burkitt's lymphoma, Wilms tumor, Prader-Willi/Angelman syndrome, ICF syndrome, dermatofibroma, hypertension, pediatric neurobiological diseases, autism, ulcerative colitis, fragile

X syndrome, and Huntington's disease.

35. Biologically effective and/or active drug, chemical substance and/or pharmaceutical composition, obtained according to a method according to any of claims 32 to 33.

36. Use of a biologically effective and/or active drug, chemical substance and/or pharmaceutical composition according to claim 35 for the treatment of a disease and/or medical condition.

37. Use according to claim 36, wherein said disease and/or medical condition is related to unwanted side effects of medicaments, cancers, dysfunctions, damages or diseases of the central nerval system (CNS), aggressive symptoms or behavioural disorders, clinical, psychological and social consequences of brain injuries, psychotic disorders and disorders of the personality, dementia and/or associates syndromes, cardiovascular diseases, malfunctions or damages, diseases, malfunctions or damages of the gastrointestine, diseases, malfunctions or damages of the respiratory system, injury, inflammation, infection, immunity and/or reconvalescence, diseases, malfunctions or damages as consequences of modifications in the developmental process, diseases, malfunctions or damages of the skin, muscles, connective tissue or bones, endocrine or metabolic diseases, malfunctions or damages, headache, and sexual malfunctions or combinations thereof.

38. Use according to claim 37, wherein said disease and/or medical condition is leukemia, head and neck cancer, Hodgkin's disease, gastric cancer, prostate cancer, renal cancer, bladder cancer, breast cancer, Burkitt's lymphoma, Wilms tumor, Prader-Willi/Angelman syndrome, ICF syndrome, dermatofibroma, hypertension, pediatric neurobiological diseases, autism, ulcerative colitis, fragile X syndrome, and Huntington's dis-

ease.

39. Method for the treatment of a disease and/or medical condition, comprising
a) providing at least one biologically effective and/or active drug, chemical substance and/or pharmaceutical composition according to a method according to any of claims 1 to 32; and
b) installing a treatment for said disease and/or medical condition comprising application of said at least one biologically effective and/or active drug, chemical substance and/or pharmaceutical composition to the patient in need.

40. Method according to claim 39, wherein said specific treatment is disease specific and/or personalised.

41. Use of a method according to claims 39 and 40 for the treatment of unwanted side effects of medicaments, cancers, dysfunctions, damages or diseases of the central nerval system (CNS), aggressive symptoms or behavioural disorders, clinical, psychological and social consequences of brain injuries, psychotic disorders and disorders of the personality, dementia and/or associates syndromes, cardiovascular diseases, malfunctions or damages, diseases, malfunctions or damages of the gastrointestine, diseases, malfunctions or damages of the respiratory system, injury, inflammation, infection, immunity and/or reconvalescence, diseases, malfunctions or damages as consequences of modifications in the developmental process, diseases, malfunctions or damages of the skin, muscles, connective tissue or bones, endocrine or metabolic diseases, malfunctions or damages, headache, and sexual malfunctions or combinations thereof.

42. Use according to claim 41 for the treatment of leukemia, head and neck cancer, Hodgkin's disease, gastric cancer, prostate cancer, renal cancer, bladder cancer, breast cancer, Bur-

kitt's lymphoma, Wilms tumor, Prader-Willi/Angelman syndrome, ICF syndrome, dermatofibroma, hypertension, pediatric neurobiological diseases, autism, ulcerative colitis, fragile X syndrome, and Huntington's disease.